UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): November 06, 2025

CLEARPOINT NEURO, INC.

(Exact name of Registrant as Specified in Its Charter)

Delaware	**001-34822**	**58-2394628**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**
120 S. Sierra Ave., Suite 100 Solana Beach, California		**92075**
(Address of Principal Executive Offices)		**(Zip Code)**

Registrant's Telephone Number, Including Area Code: 888 287-9109

(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock, $0.01 par value per share	CLPT	The Nasdaq Stock Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 2.02 Results of Operations and Financial Condition.

On November 6, 2025, ClearPoint Neuro, Inc. (the "Company") issued a press release announcing its financial results for the third fiscal quarter ended September 30, 2025. A copy of the press release is furnished herewith as Exhibit 99.1.

The information in Item 2.02 of this Form 8-K, as well as Exhibit 99.1 attached hereto, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended (the "Securities Act"), or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

Item 7.01 Regulation FD Disclosure.

On November 6, 2025, the Company posted an updated investor presentation to its website at http://ir.stockpr.com/clearpointneuro/investor-presentations. A copy of the investor presentation is being furnished herewith as Exhibit 99.2. The Company may use the investor presentation from time to time in conversations with analysts, investors and others.

The information in Item 7.01 of this Form 8-K, as well as Exhibit 99.2 attached hereto, shall not be deemed "filed" for purposes of Section 18 of the Exchange Act, nor shall it be deemed incorporated by reference in any filing under the Securities Act or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

The following exhibit is furnished herewith:

Exhibit 99.1	Press Release dated November 6, 2025
Exhibit 99.2	Investor Presentation dated November 6, 2025
Exhibit 104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

CLEARPOINT NEURO, INC.

Date: November 6, 2025

By: /s/ Danilo D'Alessandro

Danilo D'Alessandro
Chief Financial Officer

ClearPoint Neuro Reports Third Quarter 2025 Results

Site Readiness Continues for Specialized Treatment Centers Envisioned to Support a Growing Number of Cell and Gene Therapy Trial Patients and Later Commercialization

SOLANA BEACH, CA, November 6, 2025 – ClearPoint Neuro, Inc. (Nasdaq: CLPT) (the "Company"), a global device, cell, and gene therapy-enabling company offering precise navigation to the brain and spine, today announced financial results for its third quarter ended September 30, 2025.

Third Quarter Highlights

- Continued to provide supply, development, and strategic support to more than 60 active biopharma partners, including nine partner programs accepted for FDA expedited review, with many partners sharing updates on their scientific and regulatory progress at the 2025 ESGCT Annual Congress in Seville, Spain;
- Completed transition to the new Pre-clinical CRO Facility named ClearPoint Advanced Laboratories (CAL) located in Torrey Pines, California, which became operational and already began running preclinical studies early in Q4 2025;
- Announced the development and demonstration of the Company's prototype Robotic Neuro-Navigation System, which is being designed to enable the ClearPoint Neuro Navigation software to operate the KUKA LBR Med Robotic Arm to support all minimally invasive cranial surgical procedures including cell and gene therapy infusions, laser catheter placement, biopsy workflows, deep brain stimulation, and stereotactic EEG lead placements;
- Received FDA 510(k) clearance expanding compatibility of the ClearPoint PRISM Laser Therapy System with 1.5T MRI guidance in addition to the previously cleared 3T MRI guidance, opening up more than 50% of the existing market for neuro LITT;
- Announced several expanded regulatory approvals for product use in Canada, Hong Kong, and Taiwan, bringing the total number of international clearances for key therapy delivery products to 34 countries worldwide;
- Announced a signed agreement for the acquisition of IRRAS Holdings, Inc., which will expand the Company's footprint into the neurocritical care space and allow the Company to leverage an expanded commercial channel;
- Activated 5 new global customers in the third quarter;
- Reported quarterly revenue of $8.9 million, a 9% year-over-year increase compared with the third quarter of 2024 and reaffirmed the prior 2025 full year forecast narrowing the expected revenue range to between $36.0 million and $38.0 million; and
- Reported cash and cash equivalents totaling $38.2 million as of September 30, 2025.

“This is one of the most exciting times in the history of our company as we make progress across all four of our existing growth pillars and announce a plan to evolve them in line with our latest strategic direction,” commented Joe Burnett, President and CEO of ClearPoint Neuro. “We are laying the groundwork for realizing the full potential of ClearPoint Neuro as we enable our 60 plus biopharma partners to progress through the regulatory process in the United States and beyond. The scientific data emerging from several of our cell and gene therapy partners who have been selected for expedited review by the FDA has been encouraging. As we have seen from recent news, the regulatory pathway and timelines for our biopharma partners remain areas of active learning. We at ClearPoint Neuro recognize the urgency of bringing transformative therapies to patients in need and remain focused on collaborating with our partners to support their development, while also remaining committed to the highest standards of quality, safety, and consistency in therapy delivery. To advance this effort, we plan to activate additional sites to support cell and gene therapy trials and eventual commercialization with our drug delivery ecosystem. Our highest priority with the neurosurgical community is to work hand-in-hand with our biopharma partners and to identify the first 35-40 specialized treatment centers which can add 5,000 patients a year in capacity. We believe that this added site capacity using ClearPoint Neuro’s technology is crucial to standardize delivery and create consistency across sites for these new-to-world cell and gene therapies. The intent is that these experienced clinical trial sites will become the commercial deployment sites of the future, all using the ClearPoint Neuro ecosystem for MRI, CT, and Robotic Navigation, a portfolio of cannula-based routes-of-administration, quality control infusion modeling and monitoring, and expert clinical support. We believe that commercial drug delivery is the largest future revenue stream for ClearPoint Neuro, and we have only just begun to unlock its full potential.”

“However, our excitement does not begin and end with these future cell and gene therapy launches,” continued Mr. Burnett. “Our existing four pillars of growth, which will also be evolved to include IRRAS upon the closing of the acquisition, will give ClearPoint Neuro access to an existing total market valued at more than $0.5 billion, and a practical portfolio that we believe will allow us to increase our market share in each and every one of those pillars.”

“In Pillar One, Biologics and Drug Delivery, we achieved a huge milestone of activating our new ClearPoint Advanced Laboratories facility (CAL). In Q3, the team focused on setting up the new facility, establishing the foundation, writing protocols, and obtaining the various necessary certifications. We have now completed our first preclinical study for a pharmaceutical sponsor at the new facility, showing that we are officially open for business. This new facility, located in the Torrey Pines biotech region, has three potential growth vectors that we expect to monetize over the coming years as CAL allows us to 1) add capacity for much larger studies, approximately five times our prior capacity, 2) perform higher value/higher margin GLP studies including pivotal toxicology studies, and 3) offer additional services to biopharma partners increasing the potential offerings and comprehensiveness of the facility. For perspective, we have already bid out studies for 2026 and 2027 that reflect the expanded scope and greater sophistication of our new facility, which in turn results in higher value offerings for the Company. This is a huge success for the entire team to get the new facility running in such a short period of time. We expect our Biologics and Drug Delivery revenue to drive double digit growth in the fourth quarter and expand further in 2026 and 2027.”

“In Pillars Two and Three, Neurosurgery Navigation and Laser Therapy, we have continued the successful full market releases for new products, which, like in Pillar One, are designed to increase share in these existing markets. Our ClearPoint 3.0 software has now been installed at more than 50 centers in the United States and is enabling ClearPoint Neuro procedures to be performed in both the MRI suite and the operating room using CT, all with the same system. In total, we activated five new customers in the quarter. Our PRISM Laser Therapy

system just received FDA clearance expanding to compatibility with 1.5 Tesla powered magnets, opening up approximately 50% of the neuro LITT market in the United States. We expect the first installations of the 1.5 Tesla labeled product in the fourth quarter. Both 1.5T and 3.0T PRISM Laser Therapy systems have also been submitted for CE Mark approval which we expect in the second half of 2026. We also unveiled a prototype of our proprietary Robotic Neuro-Navigation System that is being designed to support all minimally invasive cranial procedures, including cell and gene therapy infusions, laser catheter placement, biopsy workflows, deep brain stimulation, and stereotactic EEG lead placements, which will make ClearPoint Neuro the only company with one software platform that can deploy navigation in three different arenas: MRI, iCT, and Robotics. This prototype received excellent early development feedback at the 75th Annual Congress of Neurological Surgeons (CNS) in Los Angeles this past month."

"In addition to advancing our existing pillars of growth, we are expanding our presence beyond the United States, with regulatory clearances now spanning 34 countries, including recent approvals in Canada, Taiwan, and Hong Kong. By making it possible for our biopharma partners to standardize and simplify every possible aspect of the surgical workflow for delivering their therapies across many geographies, we hope to reduce barriers to adoption and give our partners' therapies improved chances to succeed on a global stage."

"With the announcement of the signing of our agreement to acquire IRRAS Holdings, Inc., we expect to introduce a new fourth pillar of growth. This fourth pillar will be focused on cranial irrigation and aspiration, and will allow us to enter the substantial intracranial hemorrhage market with a potentially disruptive product in the EVD space, and gain scale by effectively doubling the size of our commercial organization. We believe that, across our evolved four growth pillars, we will have a credible path to cash breakeven and profitability without including our largest potential market of commercial cell and gene therapies in the years ahead."

Business Outlook

The Company reaffirmed its full-year guidance, narrowing the expected revenue range to between $36.0 million and $38.0 million.

Based on management's current forecasts for ClearPoint Neuro's business and our assessment of the IRRAS business, the total 2026 combined revenue for the two companies is expected to be in the range of $54.0 to $60.0 million. As with all forward-looking statements, this estimate is subject to revision based on updated information, including that arising through the post-closing integration of IRRAS. Our guidance for future financial performance is based on management's current expectations and are subject to the risks inherent in the business, which may cause the Company's actual results to differ materially from those expressed in or implied by forward-looking statements.

Financial Results – Quarter Ended September 30, 2025

Total revenue was $8.9 million for the three months ended September 30, 2025, and $8.1 million for the three months ended September 30, 2024, which represents an increase of $0.7 million, or 9%.

Biologics and drug delivery revenue, which includes sales of disposable products and services related to customer-sponsored preclinical and clinical trials, stayed relatively consistent at $4.4 million for the three months ended September 30, 2025 and 2024. Service and other revenue increased $0.7 million due to new studies performed for our partners in the three months ended September 30, 2025, offset by a decrease in product revenue due to timing of the pharmaceutical partners' clinical and preclinical trials.

Neurosurgery navigation and therapy revenue, which primarily consists of disposable product commercial sales related to cases utilizing the ClearPoint system, increased 20% to $3.4 million for the three months ended September 30, 2025, from $2.9 million for the same period in 2024. The increase is driven by higher sales of Prism Laser Therapy, and the introduction of our 3.0 operating room navigation software, which has positively impacted procedural volumes in the operating room during the three months ended September 30, 2025, compared to the same period in 2024.

Capital equipment and software revenue, consisting of sales of ClearPoint reusable hardware and software and related services, increased 25% to $1.0 million for the three months ended September 30, 2025, from $0.8 million for the same period in 2024 due to an increase in the sale of hardware and rental revenue.

The Company achieved a gross margin of 63% on its sales for the three months ended September 30, 2025, as compared to 60% in the same period in 2024. The increase in gross margin was primarily due to higher margins on biologics and drug delivery service revenue and mix of product sold for the three months ended September 30, 2025, as compared to the same period in 2024.

Operating expenses were $10.9 million for the three months ended September 30, 2025, compared with $10.0 million for same period in 2024, an increase of 9%. The increase was mainly driven by higher product and software development costs, professional services fees, and personnel-related expenses, including share-based compensation, as we increased headcount to fuel the expansion of the research and development, clinical, and support organizations.

At September 30, 2025, the Company had cash and cash equivalents totaling $38.2 million as compared to $20.1 million at December 31, 2024, with the increase resulting from the net proceeds of the note payable and stock offering of $32.0 million, partially offset by the use of $11.8 million in cash for operating activities.

On November 5, 2025, the Company entered into an agreement to access an additional $20.0 million in funding under its existing note financing arrangement with Oberland Capital, conditioned upon the closing of the Company's transaction to acquire IRRAS Holdings, Inc., and other customary closing conditions. The Company expects to use the additional funding to support integration activities, enhance working capital, and fund new growth initiatives for the combined business operations.

Teleconference Information

Investors and analysts are invited to listen to a live broadcast review of the Company's 2025 third quarter results on Thursday, November 6, 2025 at 5:00 p.m. Eastern time (2:00 p.m. Pacific time) which may be accessed online here: https://event.choruscall.com/mediaframe/webcast.html?webcastid=60S23gGB. Investors and analysts who would like to participate in the conference call via telephone may do so at (877) 407-9034, or at (201) 493-6737 if calling from outside the U.S. or Canada.

For those who cannot access the live broadcast, a replay will be available shortly after the completion of the call until December 4, 2025, by calling (877) 660-6853 or (201) 612-7415 if calling from outside the U.S. or Canada, and then entering conference I.D. number 413671. An online archive of the broadcast will be available on the Company's Investor website at https://ir.clearpointneuro.com/.

About ClearPoint Neuro

ClearPoint Neuro is a device, cell, and gene therapy-enabling company offering precise navigation to the brain and spine. The Company uniquely provides both established clinical products as well as preclinical development

services for controlled drug and device delivery. The Company's flagship product, the ClearPoint Neuro Navigation System, has FDA clearance and is CE-marked. ClearPoint Neuro is engaged with healthcare and research centers in North America, Europe, Asia, and South America. The Company is also partnered with the most innovative pharmaceutical/biotech companies, academic centers, and contract research organizations, providing solutions for direct central nervous system delivery of therapeutics in preclinical studies and clinical trials worldwide. To date, thousands of procedures have been performed and supported by the Company's field-based clinical specialist team, which offers support and services to our customers and partners worldwide. For more information, please visit www.clearpointneuro.com.

Forward-Looking Statements

Statements in this press release and in the teleconference referenced above concerning the Company's plans, growth and strategies may include forward-looking statements within the context of the federal securities laws. Statements regarding the Company's future events, developments and future performance; the Company's belief about the outcome of regulatory interactions with respect to its biotech Partners' therapies, the timing of commercialization of such therapies, and the market potential for such therapies; the continued development and commercial potential of the Company's proprietary Robotic Neuro-Navigation platform System; the size of total addressable markets or the market opportunity for the Company's products and services, including for the PRISM Laser Therapy System and the Company's preclinical CRO facility; the consummation of IRRAS Holdings, Inc. transaction and the market potential for IRRAS products; the anticipated adoption of the Company's products and services for use in the delivery of gene and cell therapies; the Company's expectations for revenues, operating expenses, and management's expectations, beliefs, plans, estimates or projections relating to the future, are forward-looking statements within the meaning of these laws. These forward-looking statements are based on management's current expectations and are subject to the risks inherent in the business, which may cause the Company's actual results to differ materially from those expressed in or implied by forward-looking statements. Particular uncertainties and risks include those relating to: the Company's biotech Partners' risks related to the ongoing conduct of their clinical studies, including the risk that such trials will be unable to demonstrate data sufficient to support further clinical development or regulatory approval; the risk that more patient data becomes available that results in a different interpretation then the data already released for gene and cell therapies; risks related to interactions with regulatory authorities, which may affect the initiation, timing and progress of clinical trials and pathways to regulatory approval of the biotech Partners' therapies; the limitation or modification of the FDA's eligibility and criteria for its expedited review programs with respect to such therapies; the commercialization and acceptance of gene and cell therapies; the Company's biotech Partner's continued use of the Company's products and services in their delivery of gene and cell therapies; the Company's ability to maintain its current relationships with its biotech Partners or enter into relationships with new partners; the Company's ability to continue to build and maintain the infrastructure and personnel needed to allow for widespread adoption of intracranial administration of gene and cell therapies; risks inherent in the research, development, and regulatory approval of the Company's new products; the future market for preclinical services and the investment required to expand such services, which could divert resources from the Company's other business operations; the possibility that the closing of the IRRAS transaction is delayed or does not occur at all because conditions to the transaction are not obtained or satisfied on a timely basis or at all; the possibility that the anticipated benefits of the IRRAS transaction are not realized when expected or at all; the Company's failure to integrate IRRAS into its business in accordance with expectations; deviations from the expected market potential of the IRRAS products; diversion of management's attention on the IRRAS proposed transaction; macroeconomic and inflationary conditions; regulatory and policy uncertainty; the introduction of or changes in tariffs, sanctions, or trade barriers; changes in monetary policy; geopolitical trends, such as protectionism and economic nationalism; the Company's ability to market, commercialize and achieve broader market acceptance

for new products and services offered by the Company; the availability of additional funding to support the Company's research and development programs; the ability of the Company to manage the growth of its business; and the Company's ability to attract and retain its key employees. For a detailed description of the Company's risks and uncertainties, you are encouraged to review its documents filed with the SEC including the Company's recent filings on Form 8-K, Form 10-K and Form 10-Q. You are cautioned not to place undue reliance on forward-looking statements, which speak only as of the date on which they were made. The Company undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made, except as required by law.

Contact:

Investor Relations:
Danilo D'Alessandro, Chief Financial Officer
(888) 287-9109 ext. 3
ir@clearpointneuro.com

CLEARPOINT NEURO, INC.
Consolidated Statements of Operations
(Unaudited)
(in thousands, except for share and per share data)

	For the Three Months Ended September 30,	
	2025	**2024**
Revenue:		
Product revenue	$ 5,361	$ 5,474
Service and other revenue	3,500	2,648
Total revenue	8,861	8,122
Cost of revenue	3,261	3,275
Gross profit	5,600	4,847
Research and development costs	3,452	3,315
Sales and marketing expenses	3,838	3,549
General and administrative expenses	3,586	3,141
Operating loss	(5,276)	(5,158)
Other income (expense):		
Other expense, net	(64)	(11)
Interest (expense) income, net	(543)	209
Net loss before income taxes	(5,883)	(4,960)
Income tax expense	(8)	(14)
Net loss	$ (5,891)	$ (4,974)
Net loss per share attributable to common stockholders:		
Basic and diluted	$ (0.21)	$ (0.18)
Weighted average shares outstanding:		
Basic and diluted	28,427,574	27,591,623

	For the Nine Months Ended September 30,	
	2025	**2024**
Revenue:		
Product revenue	$ 16,649	$ 14,053
Service and other revenue	9,912	9,566
Total revenue	26,561	23,619
Cost of revenue	10,273	9,259
Gross profit	16,288	14,360
Research and development costs	10,660	9,060
Sales and marketing expenses	11,691	10,673
General and administrative expenses	11,056	8,725
Operating loss	(17,119)	(14,098)
Other income (expense):		
Other expense, net	(112)	(32)
Interest (expense) income, net	(472)	646
Net loss before income taxes	(17,703)	(13,484)
Income tax expense	(51)	(44)
Net loss	$ (17,754)	$ (13,528)
Net loss per share attributable to common stockholders:		
Basic and diluted	$ (0.63)	$ (0.50)
Weighted average shares outstanding:		
Basic and diluted	28,137,528	26,840,119

CLEARPOINT NEURO, INC.

Consolidated Balance Sheets

(in thousands, except for share and per share data)

	September 30, 2025 (Unaudited)	December 31, 2024
ASSETS		
Current assets:		
Cash and cash equivalents	$ 38,221	$ 20,104
Accounts receivable, net	4,000	4,713
Inventory, net	6,583	6,863
Prepaid expenses and other current assets	2,525	1,683
Total current assets	51,329	33,363
Property and equipment, net	2,114	2,005
Operating lease, right-of-use assets	5,955	3,086
Other assets	959	735
Total assets	$ 60,357	$ 39,189
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 723	$ 1,340
Accrued compensation	3,516	4,885
Other accrued liabilities	1,748	1,450
Operating lease liabilities, current portion	347	557
Contract liabilities, current portion	1,719	2,121
Total current liabilities	8,053	10,353
Operating lease liabilities, net of current portion	6,195	3,011
Contract liabilities, net of current portion	769	436
Long-term note payable, net	29,203	—
Other long-term liabilities	263	—
Total liabilities	44,483	13,800
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.01 par value; 25,000,000 shares authorized; none issued and outstanding at September 30, 2025 and December 31, 2024	—	—
Common stock, $0.01 par value; 90,000,000 shares authorized at September 30, 2025 and December 31, 2024; 28,428,176 and 27,617,415 shares issued and outstanding at September 30, 2025 and December 31, 2024, respectively	284	276
Additional paid-in capital	224,714	216,483
Accumulated deficit	(209,124)	(191,370)
Total stockholders' equity	15,874	25,389
Total liabilities and stockholders' equity	$ 60,357	$ 39,189

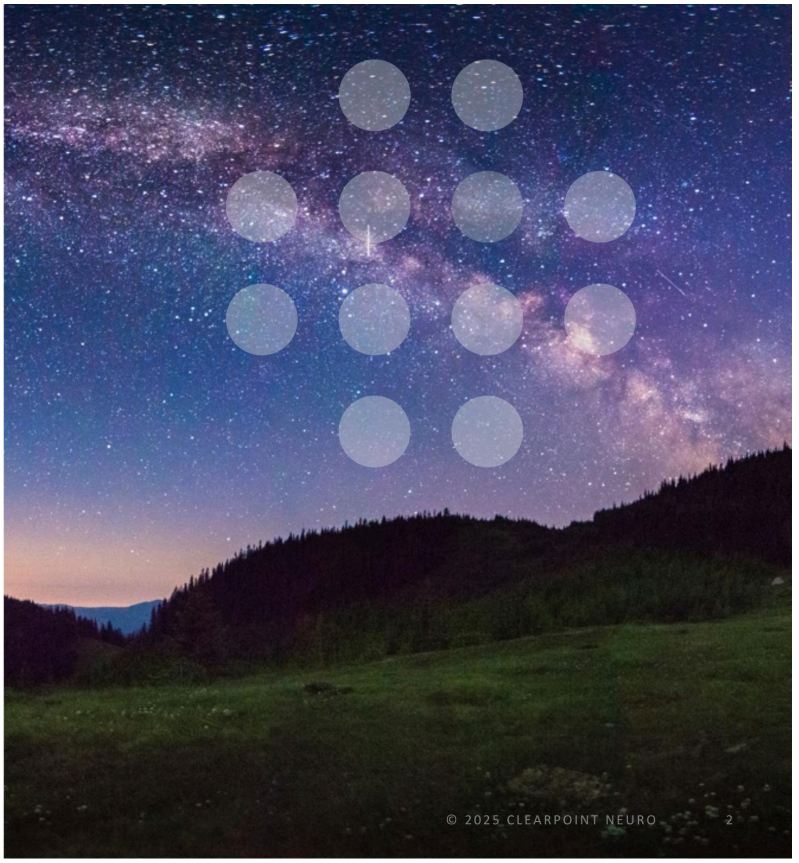
CLEARPOINT NEURO, INC.
Consolidated Statements of Cash Flows
(Unaudited)
(in thousands)

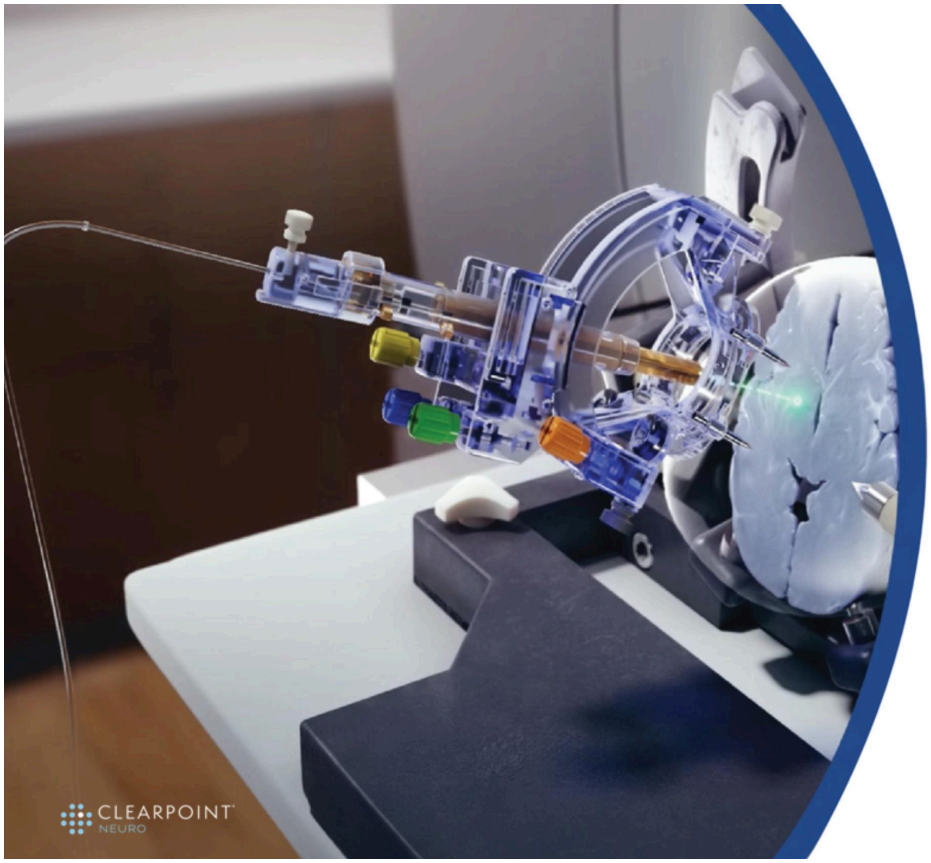
	For the Nine Months Ended September 30,	
	2025	**2024**
Cash flows from operating activities:		
Net loss	$ (17,754)	$ (13,528)
Adjustments to reconcile net loss to net cash flows from operating activities:		
Allowance for credit losses (recoveries)	217	(507)
Depreciation and amortization	565	740
Share-based compensation	6,199	5,204
Payment-in-kind interest	490	—
Amortization of debt issuance costs and original issue discounts	60	51
Amortization of lease right of use assets, net of accretion in lease liabilities	821	692
Increase (decrease) in cash resulting from changes in:		
Accounts receivable	497	(157)
Inventory, net	(16)	434
Prepaid expenses and other current assets	(696)	88
Other assets	(192)	(40)
Accounts payable and accrued expenses	(1,251)	1,373
Lease liabilities	(716)	(635)
Contract liabilities	(69)	(1,422)
Net cash flows from operating activities	(11,845)	(7,707)
Cash flows from investing activities:		
Purchases of property and equipment	(473)	(12)
Net cash flows from investing activities	(473)	(12)
Cash flows from financing activities:		
Proceeds from offerings of common stock, net of offering costs	3,263	16,183
Proceeds from issuance of note payable, net of financing costs and discount	28,653	—
Repayment of 2020 senior secured convertible note	—	(10,000)
Proceeds from stock option exercises	49	21
Payments for taxes related to net share settlement of equity awards	(1,661)	(340)
Proceeds from issuance of common stock under employee stock purchase plan	311	288
Net cash flows from financing activities	30,615	6,152
Net change in cash, cash equivalents and restricted cash	18,297	(1,567)
Cash, cash equivalents and restricted cash, beginning of period	20,104	23,140
Cash, cash equivalents and restricted cash, end of period	$ 38,401	$ 21,573
Cash and cash equivalents	38,221	21,573
Restricted cash included in other assets, non-current	180	—
Total cash, cash equivalents and restricted cash	$ 38,401	$ 21,573
SUPPLEMENTAL CASH FLOW INFORMATION		
Cash paid for:		
Income taxes	$ 69	$ 41
Interest	$ 490	$ 480


CLEARPOINT
NEURO
WHEN YOUR PATH IS UNCLEAR,
WE POINT THE WAY.
Nasdaq: CLPT
November 2025

DISCLAIMER

This presentation and discussion contain forward-looking statements within the context of the federal securities laws, including the Company's expectation for revenues, gross margin, the adequacy of cash and cash equivalent balances to support operations and meet future obligations, the future market of the Company's products and services, the Company's belief about the outcome of regulatory interactions with respect to its biotech partners' therapies, the timing of commercialization of such therapies, the market potential for such therapies, the anticipated adoption of the Company's products and services for use in the delivery of gene and cell therapies, and other performance and results. These forward-looking statements are based on management's current expectations and are subject to the risks inherent in the business, which may cause the Company's actual results to differ materially from those expressed in or implied by forward-looking statements. Particular uncertainties and risks include those relating to: macroeconomic and inflationary conditions; the introduction of or changes in tariffs, sanctions, or trade barriers; changes in monetary policy; geopolitical trends, such as protectionism and economic nationalism; future revenue from sales of the Company's products and services; the Company's ability to market, commercialize and achieve broader market acceptance for new products and services offered by the Company; the ability of the Company's biotech partners to achieve commercial success, including their use of the Company's products and services in their delivery of therapies; the Company's ability to maintain its current relationships with biotech partners or enter into new relationships with such partners; the Company's biotech partners' risks related to the ongoing conduct of their clinical studies, including the risk that such trials will be unable to demonstrate data sufficient to support further clinical development or regulatory approval; the risk that more patient data becomes available that results in a different interpretation then the data already released for gene and cell therapies; risks related to interactions with regulatory authorities, which may affect the initiation, timing and progress of clinical trials and pathways to regulatory approval of the biotech partners' therapies; the limitation or modification of the FDA's eligibility and criteria for its expedited review programs with respect to such therapies; the commercialization and acceptance of gene and cell therapies; the Company's biotech partner's continued use of the Company's products and services in their delivery of gene and cell therapies; the Company's expectations, projections and estimates regarding expenses, future revenue, capital requirements, and the availability of and the need for additional financing; the Company's ability to obtain additional funding to support its research and development programs; the ability of the Company to manage the growth of its business; the Company's ability to attract and retain its key employees; and risks inherent in the research, development, and regulatory approval of new products and the new products of its biotech partners. For a detailed description of the Company's risks and uncertainties, you are encouraged to review its documents filed with the SEC including the Company's recent filings on Form 8-K, Form 10-K and Form 10-Q. You are cautioned not to place undue reliance on forward-looking statements, which speak only as of the date on which they were made. The Company undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made, except as required by law.





CLEARPOINT®
NEURO

OUR COMPANY

We Enable Cell, Gene and Device Therapies by Offering Precise Navigation to the Brain and Spine

Our Unique Platform Includes Both Proven Clinical Products Used by Neurosurgeons, and Drug Development Services Used by BioPharma Partners

CLEARPOINT NEURO EXECUTIVE SUMMARY

A UNIQUE PLATFORM TECHNOLOGY USED FOR CELL AND GENE THERAPY DELIVERY

15+ years building a complete drug delivery ecosystem including navigation solutions, predictive modeling, delivery devices, infusion monitoring software and clinical case support

A $10B POTENTIAL MARKET DIVERSIFIED ACROSS 60+ PARTNERS, 20+ INDICATIONS*

Combination device success, proprietary technology and deep FDA experience provide our BioPharma partners with a meaningful head start, and our investors with a Portfolio-like biotech strategy

100+ ACTIVE GLOBAL CENTERS

An expanding global installed base of regional treatment centers are scaling capacity to be ready for additional cell and gene therapy patients to be treated with a unified platform

CURRENT PORTFOLIO PROVIDES ACCESS TO A ≈$500M MARKET OPPORTUNITY TODAY

Evolved beyond the MRI and into operating room CT navigation, laser ablation therapy, surgical access tools and preclinical CRO services which fuel growth via new product launches and provide path to profitability

A GROWING & PASSIONATE TEAM

Our dedicated team of engineers, scientists and clinical specialists wake up every morning focused on the future of neurosurgery and drug delivery - *This is all that we do...*

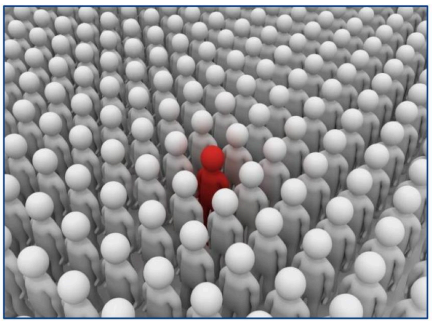
*Including indications for all cell, gene, and device therapies enabled by ClearPoint Neuro technologies

The Future of Cell and Gene Therapy is Not Coming… **It is HERE TODAY**

More than **30 million people** in the U.S. are estimated to suffer from **severe and debilitating neurological disorders:**

- Parkinson's Disease (≈1,000,000)
- Essential Tremor (≈7,000,000)
- Epilepsy (≈2,900,000)
- Huntington's Disease (≈41,000)
- Rare Childhood Genetic Disorders (≈25,000)
- Dementia and Alzheimer's Disease (≈6,900,000)
- Tumor and Glioblastoma (≈280,000)
- Severe OCD (≈1,000,000)
- Treatment Resistant Depression (≈2,900,000)
- ALS and Spinal Cord Injury (≈300,000)
- Stroke Rehabilitation (≈7,000,000)
- Neuropathic Pain (≈2,000,000)

Neurological diseases cost Americans nearly $800 billion annually. The only way to decrease these costs is to improve treatment.



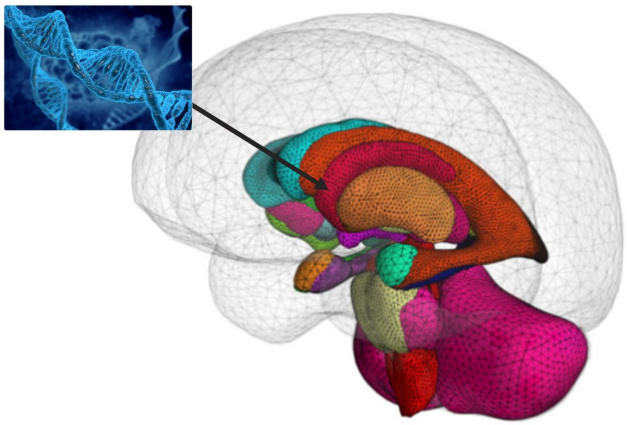
Despite some available treatments, **very few of these patients** undergo a direct surgical intervention to improve their **quality of life**…

Sources on file at ClearPoint Neuro

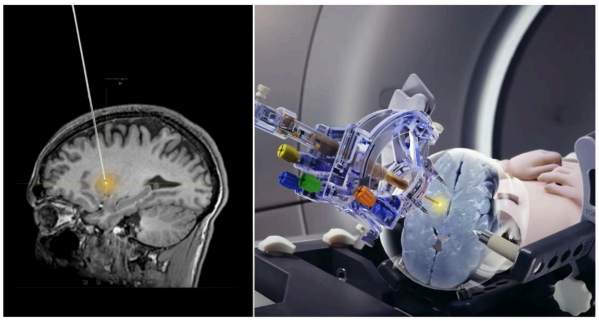
The Future of Cell and Gene Therapy is Not Coming… **It is HERE TODAY**

Our Goal is to Help More Patients by Addressing **Two Primary Barriers to Treatment**

1 **We will partner** to Develop Device, Cell and Gene Therapies that may **cure the underlying disease and restore function…**



2 **We will Enable** fast, minimally invasive, asleep procedures for **a more comfortable and predictable patient experience…**



The Future of Cell and Gene Therapy is Not Coming… **It is HERE TODAY**

1 Partner has received FDA approval for a neuro gene therapy that is co-labeled with ClearPoint

FDA NEWS RELEASE

FDA Approves First Gene Therapy for Treatment of Aromatic L-amino Acid Decarboxylase Deficiency

For Immediate Release:
November 14, 2024

The U.S. Food and Drug Administration approved Kebilidi (eladocagene exuparvovec-tneq), an adeno-associated virus vector-based gene therapy indicated for the treatment of adult and pediatric patients with aromatic L-amino acid decarboxylase (AADC) deficiency. Kebilidi is the first FDA-approved gene therapy for treatment of AADC deficiency.

"Clinical advancements in the field of gene therapy continue to lead to the discovery and availability of innovative treatment options for rare diseases that are otherwise difficult to manage," said Peter Marks, M.D., Ph.D., director of the FDA's Center for Biologics Evaluation and Research (CBER). "Today's approval underscores our commitment to help make safe and effective treatments available for patients in need."

The FDA also authorized the SmartFlow Neuro Cannula, an infusion tube inserted into a target in the brain (parenchymal tissue), to deliver Kebilidi. The SmartFlow Neuro Cannula is currently the only FDA authorized device indicated for use to administer Kebilidi. The FDA granted authorization of the SmartFlow Neuro Cannula to ClearPoint Neuro, Inc.

9 Partners have programs selected for expedited review - the FDA recognizes the urgency

FAST TRACK
Expedites development and review of drugs to treat **serious conditions** and fill an **unmet medical need**.

REGENERATIVE MEDICINE ADVANCED THERAPY RMAT
Granted to regenerative medicines, such as **gene and cell therapies**, based on potential to **address a major unmet medical need**.

PRIORITY REVIEW
For drugs that offer **major advances in treatment** over existing therapies. FDA goal is to act **within 6 months**.

The Future of Cell and Gene Therapy is Not Coming…**it is HERE TODAY**

9 Active Clinical-Stage Partners have been selected for expedited review, including:

	Indication	RMAT	Fast Track	Clinical Status
PTC THERAPEUTICS	AADC Deficiency	-	-	**Approved**
uniQure	Huntington's Disease	✓	-	Trials in US, EU
BlueRock THERAPEUTICS	Parkinson's Disease	✓	-	Trials in NorthAm
NEURONA THERAPEUTICS	Epilepsy (MTLE)	✓	-	Trials in the US
AskBio	Parkinson's Disease	✓	✓	Trials in US, EU
REGENXBIO	Hunter Syndrome (MPSII)	✓	✓	Trials in US, Brazil
Aspen NEUROSCIENCE	Parkinson's Disease	-	✓	Trials in the US
AVIADOBIO	Frontotemporal Dementia	-	✓	Trials in US, EU
Undisclosed	Friedreich's Ataxia	-	✓	Trials in the US

In 2025 Our Journey Enters the **NEXT CHAPTER**

2010 - 2020

Discovery. Design.

- Neurosurgeon-Led Ideation
- Unique MRI Navigation
- Initial FDA Clearance and Product Revenue
- Accumulation of Clinical Trial Experience Using SmartFlow
- Maestro A.I. Software Development
- Initial IP Generation and Licenses
- NASDAQ Listed

2021 - 2024

Funded. Foundation.

- 100+ Activated Customers
- 60+ Biopharma Partners
- 20+ Potential Disease Indications*
- Preclinical Team Creation
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- Laser Therapy Product Launch
- 100+ Owned & Licensed Patents
- EU MDR Certification
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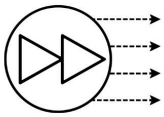
- Leadership Team Complete

2025 - 2027



Fast. Forward.

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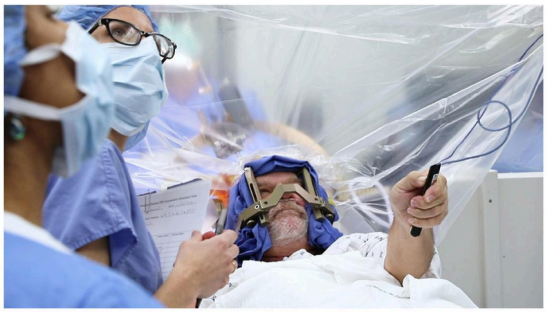
- Additional Global Regulatory Approvals Beyond the U.S. and E.U.

*Including indications for all cell, gene, and device therapies enabled by ClearPoint Neuro technologies

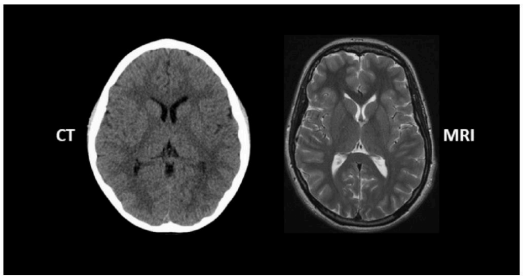
Our Start: Unique Neurosurgery Navigation Guided by Live MRI

Neurosurgery has traditionally been done via open craniotomy or by using CT guidance in the operating room



The historical limitations of CT accuracy would often require patients to remain awake for hours-long brain surgery to confirm the location and impact of technologies like DBS

ClearPoint believed that building a navigation system that could harness the power of live MRI would be accurate enough that **the patient could be comfortably asleep for this minimally invasive procedure**



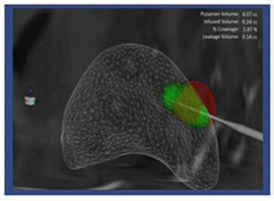
The ClearPoint SmartFrame family of products uses MR-safe materials and enables surgeons to **Decide, Guide & Confirm using live MR Imaging to achieve sub-millimetric accuracy**

Discovery. Design.

Our Start: Decide, Guide & Confirm

Pre-Plan Trajectory
and **D E C I D E**
Entry Point

Automatically **G U I D E**
Precision Adjustments
Prior to Insertion



C O N F I R M
Quality of Delivery Into
Permanent Record

Three Primary Use Cases demonstrate the value of the ClearPoint Neuro Navigation System:

1. Functional neurosurgeons could confidently place DBS electrodes with the **patient comfortably asleep**

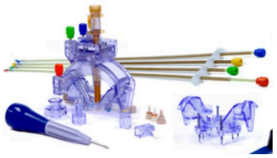
2. Neuro-oncologists could perform **entire tumor laser ablations in one room instead of having to transport the patient from the OR to the MRI**

3. BioPharma researchers could confirm that cell and gene therapies are not only **delivered to a precise location**, but could also **confirm proper coverage** of the target structure before closing the patient

Discovery. Design.

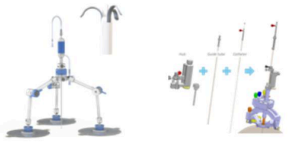
Our Start: Assemble the Building Blocks

Leveraging our **unique platform** and **dedicated team,** we developed and acquired essential technologies necessary to complete the entire ecosystem for MR-Guided Navigation with a focus on cell and gene therapy delivery

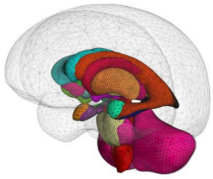


SmartFrame XG and Surgical Accessory Kit

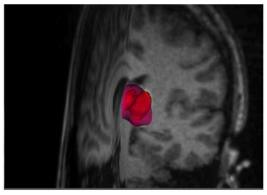
SmartFlow Cannula
(FDA and CE Marked, more than 8,000 cannulas sold to date)



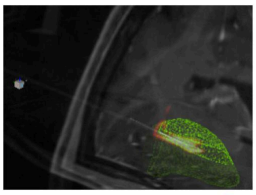
Radial Branching Cell Therapy Devices and Spinal Infusion Anchors
(Investigational Use Only)



ClearPoint Maestro Brain Model Segmentation and Image Fusion



3D Peri-procedural Infusion Monitoring Software
(Investigational Use Only)



Biophysical Modeling of patient specific drug infusions
(Investigational Use Only)

Funded. Foundation.

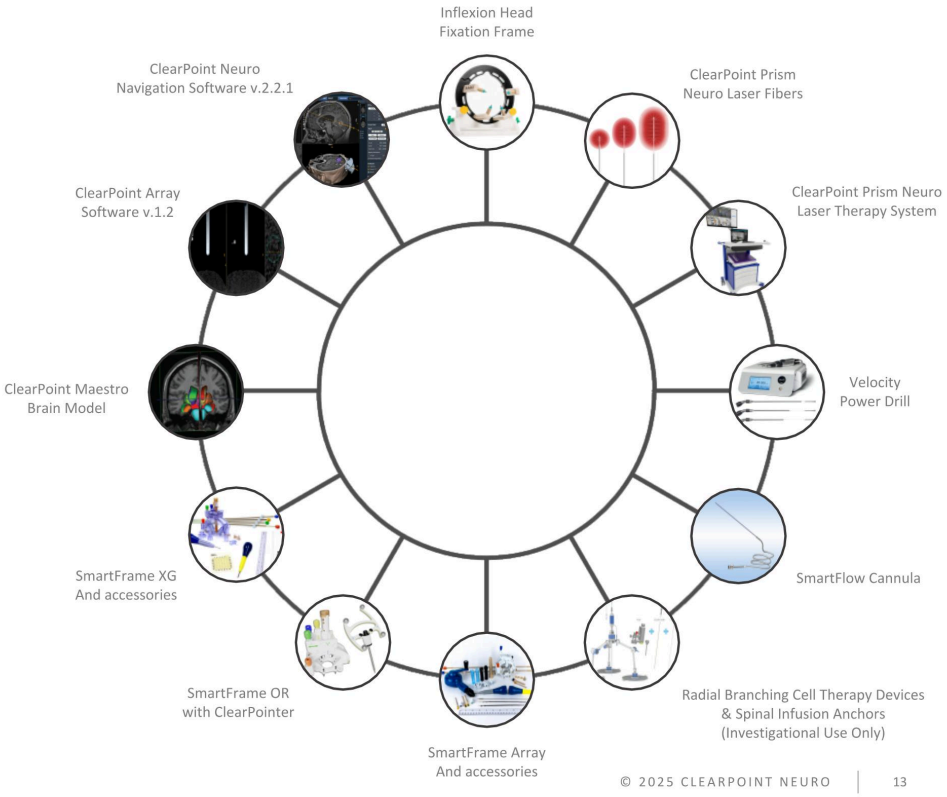
Building the Business

ClearPoint Neuro built a **complete and unique ecosystem of clinical and preclinical products and has achieved regulatory approvals in multiple geographies**

This proven technology has **more than 10 years of experience and been used in more than 7,000 procedures** to date

Demand for our platform has grown driven by the **promise of cell and gene therapies, new DBS indications, and the expansion of laser therapy**

ClearPoint Neuro **activated a record 25 new Global Customers in 2024**



Funded. Foundation.

Building the Business: Our Four-Pillar Growth Strategy Remains **Our Foundation**

1 BIOLOGICS & DRUG DELIVERY

PTC THERAPEUTICS · uniQure · Spark THERAPEUTICS · Aspen NEUROSCIENCE · ucb · NEURONA THERAPEUTICS · BlueRock Therapeutics · AskBio · AVIADOBIO · charles river

60+ INDUSTRY & ACADEMIC PARTNERS

2 NEUROSURGERY NAVIGATION

Abbott · Boston Scientific · Medtronic · NEUROPACE

3 LASER THERAPY & ACCESS

CLEARPOINT PRISM NEURO LASER THERAPY SYSTEM · MONTERIS MEDICAL · Medtronic VISUALASE · adeor MEDICAL

4 GLOBAL SCALE

100+ GLOBAL CENTERS

SIEMENS Healthineers · IMRIS · GE · PHILIPS · Medtronic

CLEARPOINT NAVIGATION IS COMPATIBLE WITH MAJOR DIAGNOSTIC AND INTRAOPERATIVE MRI AND CT SCANNERS

CLEARPOINT NEURO

United States Centers
International Centers
Preclinical Centers

Albany Medical Center Hospital
Banner Health Tucson
Baptist Hospital of Miami
Baptist Memorial Hospital-Memphis
Barnes-Jewish Hospital
Barrow Neurological Institute/St. Joseph's Hospital
BayCare Health System
Benioff Children's Hospital
Beth Israel Deaconess
Boston Children's Hospital
Brigham & Women's Hospital
Brown University / Rhode Island Hospital
Carilion Clinic
Children's Hospital of Alabama
Children's Mercy Hospital
Children's National Hospital
CHOA Scottish Rite
Cincinnati Children's Hospital
Cincinnati Jewish Hospital
Cleveland Clinic Hospital
Cook Children's Hospital
Cooperman Barnabas Medical Center
Corewell Health
Dallas Presbyterian Hospital
Dartmouth-Hitchcock
Duke University
Emory University
Froedtert Hospital
Hackensack University Medical Center
Henry Ford Health
Henry Ford West Bloomfield Hospital
Hospital of University Pennsylvania
Houston Methodist Hospital
INOVA Fairfax
JFK University Medical Center
Johns Hopkins University
Kaleida Health
Kettering Health
Loma Linda University Health
Lucile Packard Children's Hospital
Massachusetts General Hospital
Mayo Clinic in Arizona
Mayo Clinic in Florida
MD Anderson Cancer Center
MedStar Georgetown University Hospital
Memorial Sloan-Kettering Cancer Center
Methodist Hospital San Antonio
Mt. Sinai West
Nationwide Children's
Northwestern Central DuPage
Ochsner Medical Center
Ohio State East Hospital
Ohio State University
Oregon Health & Science University
Orlando Health Arnold Palmer Hospital for Children
Prisma Health
Riverside Methodist Hospital
Rutgers/Robert Wood Johnson
San Francisco VA Health Care System
Southern Arizona VA Health Care System
Stanford University
Sunnyside Kaiser Permanente
Tampa General Hospital
Texas Children's Hospital
University Hospital San Antonio
University of Alabama at Birmingham
University of California Los Angeles
University of California San Diego
University of California San Francisco
University of Colorado
University of Florida Jacksonville
University of Kansas Medical Center
University of Maryland Medical Center
University of Michigan
University of Minnesota
University of North Carolina (UNC) Health
University of Oklahoma Medical Center
University of Utah
University of Wisconsin
USC Keck Hospital
UT Southwestern Medical Center
Wolfson Children's Hospital
Yale University

Charité – Universitätsmedizin Berlin (Berlin, Germany)
Fondazione I.R.C.C.S. Istituto Neurologico Carlo Besta (Milan, Italy)
Great Ormond Street Hospital (London, UK)
Hôpital Fondation Rothschild (Paris, France)
Hospital Israelita Albert Einstein (São Paulo, Brazil)
Hospital Santa Joana (Recife, Brazil)
Mazowiecki Szpital Bródnowski (Warsaw, Poland)
Policlinico Umberto I (Rome, Italy)
Rigshospitalet (Copenhagen, Denmark)
Sahlgrenska Universitetssjukhuset (Gothenburg, Sweden)
Skänes Universitetssjukhus Lund (Lund, Sweden)
Santobono Children's Hospital (Naples, Italy)
Universitätsklinikum Tübingen (Tübingen, Germany)
Universitätsklinikum Düsseldorf (Düsseldorf, Germany)
Universitätsklinikum Freiburg (Freiburg, Germany)
University Hospital of Wales (Cardiff, UK)

Charles River Labs (Laval, Canada)
Charles River Labs (Lyon, France)
Charles River Labs (Mattawan, Michigan)
Children's Hospital of Philadelphia
Labcorp (Madison, Wisconsin)
Prisys Biotechnologies (Shanghai, China)
IDU GENOV - Institut du Cerveau (Paris, France)
University of Pennsylvania Gene Therapy

100+
GLOBAL CENTERS NOW ACTIVATED

Funded. Foundation.

Building the Business

We have invested in the Development, Quality and Supply infrastructure to build confidence for both hospitals and BioPharma partners

We are not a start-up company but an **experienced and sophisticated medical device extension** for any cell and gene therapy company

ClearPoint Neuro assets available to our partners:

- HQ & Training Facility in Solana Beach, California
- Research Laboratory in San Diego, California
- Manufacturing Facility in Carlsbad, California
- ISO 13485 / MDSAP / EU MDR Certified QMS
- Significant and positive experience with BioPharma Audits, FDA and Global Notified Body inspections

Funded. Foundation.

Building the Business

Key Products: FDA CE Marked Platforms

HEADQUARTERS
Solana Beach, CA

MANUFACTURING
Carlsbad, CA

2024 REVENUE
$31.4M[A]

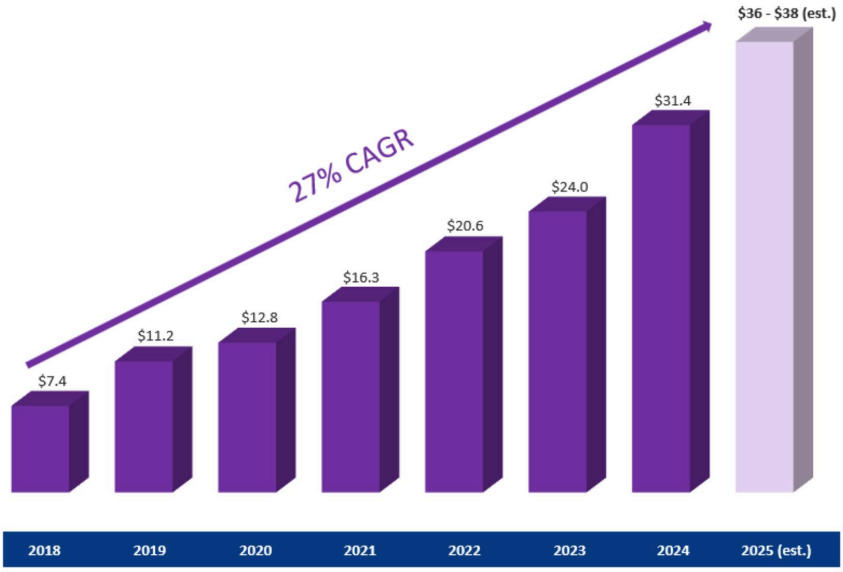
CASH & CASH EQUIVALENTS
$38.2M[B]

PATENTS ISSUED
100+[C]

GROSS MARGIN
61%[B,D]

EMPLOYEES
100+

2024 Operational Cash Burn
($9.0M)[A]



(A) For the year ended December 31, 2024
(B) Unaudited, as of, and for the quarter ended, September 30, 2025
(C) Including owned and licensed patents
(D) For the Trailing Twelve Months (TTM)

Building the Business

EXECUTIVE LEADERSHIP TEAM

Experienced leadership team with decades of leadership in medical devices, pharmaceuticals, and clinical research.

Joe Burnett
President &
Chief Executive Officer

Danilo D'Alessandro
Chief Financial
Officer

Jeremy Stigall
Chief Business
Officer

Mazin Sabra
Chief Operating
Officer

Ellisa Cholapranee
General
Counsel

Megan Faulkenberry
Vice President
of Quality

Lyubomir Zagorchev, PhD
Vice President of Clinical
Science & Applications

Mary McNamara-Cullinane
Vice President
of Regulatory Affairs

Ernesto Salegio, PhD
Vice President of Translational
& Preclinical Research

Rob Korn
Vice President
U.S. Commercial Sales

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2021 - 2024

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- 60+ Biopharma Partners
- 20+ Potential Disease Indications*
- Preclinical Team Creation
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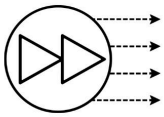
2025 - 2027



Fast. Forward.

- Grow into an estimated, existing $500M Market Opportunity
- 150 Activated Customers
- First Commercial CGT Launched
- GLP Preclinical Capability
- Operating Room Nav Growth
- Laser Therapy Growth
- MR Drill and Access Growth
- 'Harmony' Software Launch
- New Routes of Administration
- Operational Cash Breakeven

2028+

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*Including indications for all cell, gene, and device therapies enabled by ClearPoint Neuro technologies

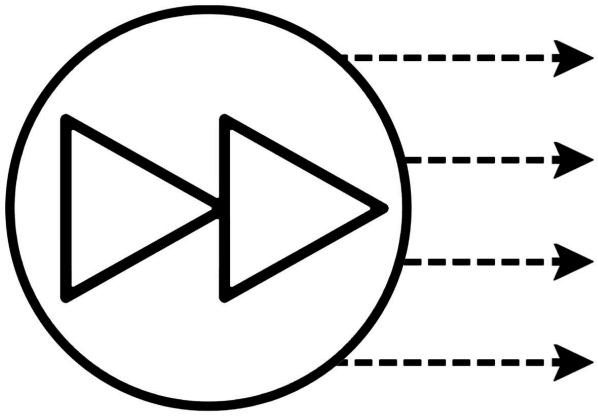
We are Pointing the Way for a Cell and Gene Therapy Future: **Fast. Forward.**

Our commitment to hospitals & BioPharma partners is to help prepare for tens-of-thousands of anticipated new patients who will be seeking these restorative therapies

1. **Extend Our Lead** in Neuro Drug Delivery by leveraging our complete and unique ecosystem of both products and drug development services

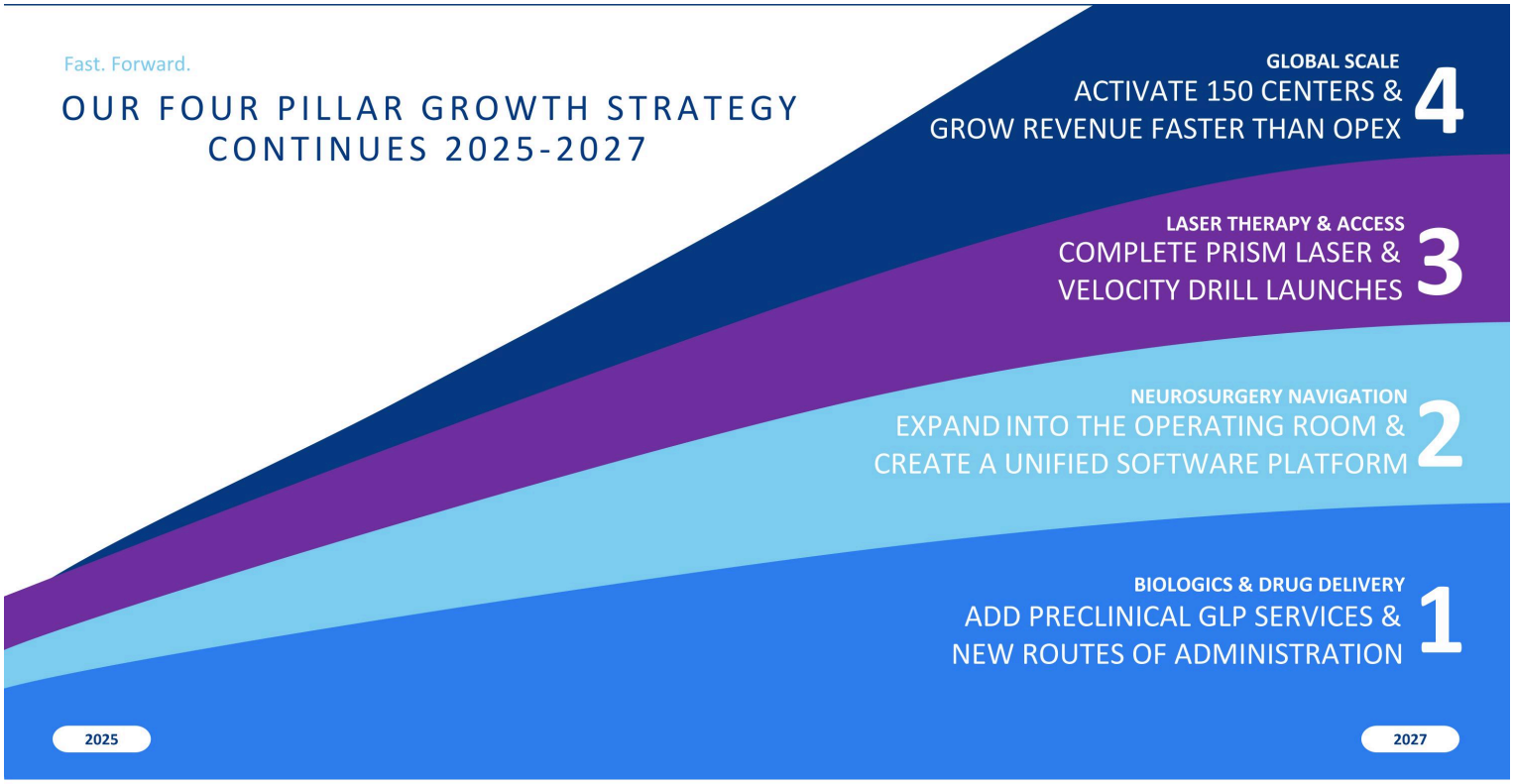
2. **Evolve our Portfolio** to focus on fast, simple, predictable procedures in both the MRI and Operating Room to increase hospital throughput

3. **Expand our Base** of global activated centers to increase capacity and ensure access of these novel cell and gene therapies



Fast. Forward.

OUR FOUR PILLAR GROWTH STRATEGY CONTINUES 2025-2027



Fast. Forward.

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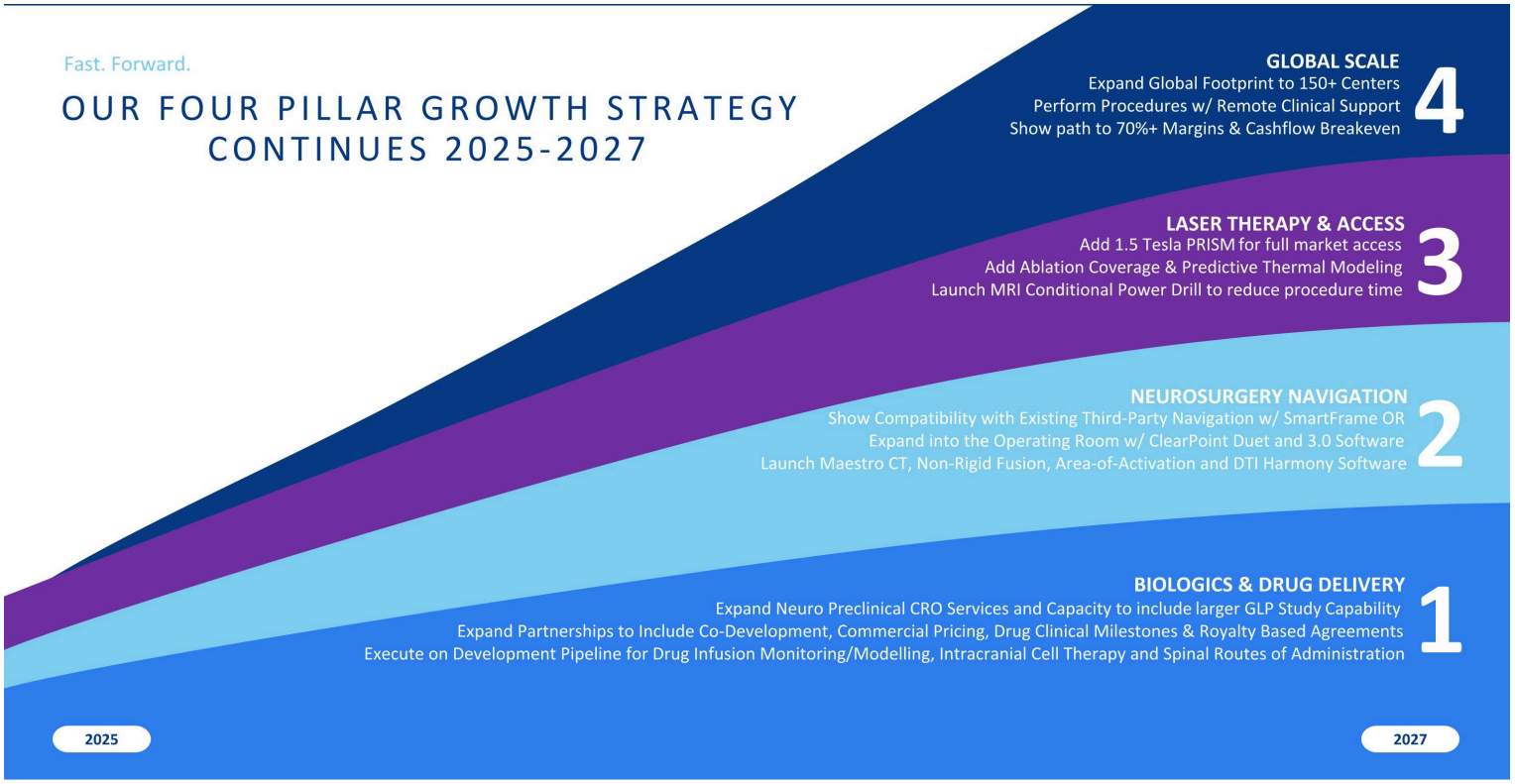
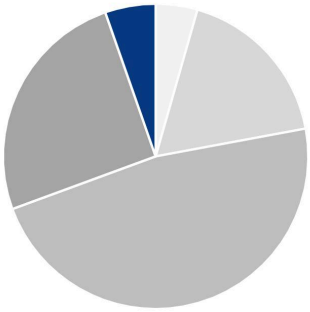


CLEARPOINT NEURO

GLP Services & New Routes of Administration

2025 Estimated Preclinical & Clinical Trial Market (≈$300M)



- Consulting, Bench Testing and Co-Development Services
- Pilot Pre-Clinical Testing (non-GLP)
- FDA Submission Preclinical Testing (GLP)
- Clinical Trial Products & Support Services
- Current CLPT Share

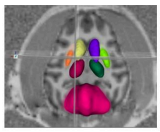
Estimated Market Size, Growth Drivers, and Share Drivers are based on internal estimates and assumptions, market trends, and customer insights. Assumptions may not reflect actual future performance.

Market Growth Drivers:

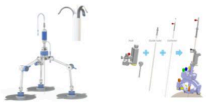
- Improved BioPharma funding environment
- Additional cell and gene therapies entering the 'funnel'
- Partner progression into larger spend GLP studies and clinical trials
- Successful implementation of FDA 'Expedited Review' pathways including RMAT offering faster clinical trials and less capital required

Market Share Drivers:

- Addition of GLP capability and increased study capacity
- Expansion to ClearPoint Advanced Laboratories ('CAL')
- Product portfolio expansion including new routes of administration
- More custom-development and strategic partnerships w/ BioPharma



GLP Preclinical Services and Image Analysis Lab (Expected 2H 2025)



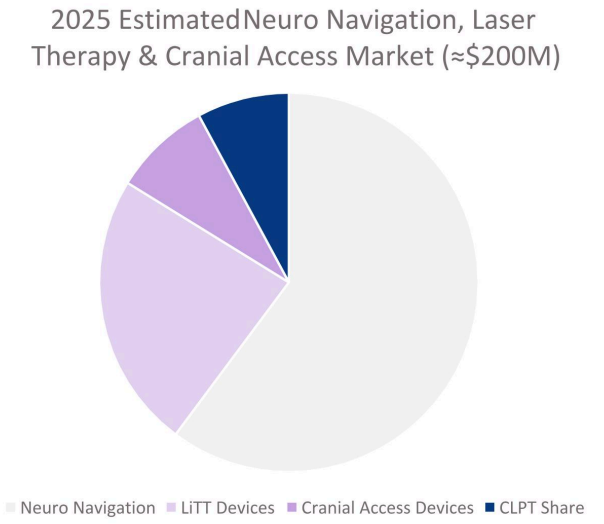
New Routes of Administration (Investigational Use Only)

Coverage Estimation and Biophysical modeling (Investigational Use Only)

Assumptions:
150 active cell and gene therapy programs globally
7.5 years average program duration
200 patients studied clinically on average as part of trials

Fast. Forward.

Neuro Navigation, Therapy and Access Product Growth



Estimated Market Size, Growth Drivers, and Share Drivers are based on internal estimates and assumptions, market trends, and customer insights. Assumptions may not reflect actual future performance.

Market Growth Drivers:

- Asleep DBS FDA Clearance and Patient Awareness
- New DBS Indications including Epilepsy, OCD, Depression, BCI
- Increased hospital throughput of laser therapy compared to open surgery
- Improved laser insurance decisions and awareness
- Additional global approvals

Market Share Drivers:

- 3.0 Software for proficient, mirrored CLPT workflow in the MRI and OR
- Asleep, simultaneous workflows for fast procedures, low radiation
- 1.5 Tesla PRISM Laser approval for full market access
- Velocity Alpha MR Drill for faster cranial access times

SmartFrame OR and ClearPointer™

ClearPoint 3.0 Software w/ CT Functionality (FDA Cleared January 2025)

SmartFrame DUET w/ flexible MRI & CT workflows (Expected 2026)

1.5 Tesla PRISM (FDA Cleared September 2025)

Adeor Velocity MRI Conditional Power Drill (Pending FDA Clearance)

In 2025 Our Journey Enters the **NEXT CHAPTER**

2010 - 2020

Discovery. Design.

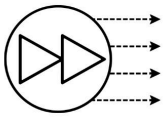
- Neurosurgeon-Led Ideation
- Unique MRI Navigation
- Initial FDA Clearance and Product Revenue
- Accumulation of Clinical Trial Experience Using SmartFlow
- Maestro A.I. Software Development
- Initial IP Generation and Licenses
- NASDAQ Listed

2021 - 2024

Funded. Foundation.

- 100+ Activated Customers
- 60+ Biopharma Partners
- 20+ Potential Disease Indications*
- Preclinical Team Creation
- Operating Room Product Launch
- Laser Therapy Product Launch
- 100+ Owned & Licensed Patents
- EU MDR Certification
- Expanded, Audit-Ready Manufacturing in California
- Leadership Team Complete

2025 - 2027



Fast. Forward.

- Grow into an estimated, existing $500M Market Opportunity
- 150 Activated Customers
- First Commercial CGT Launched
- GLP Preclinical Capability
- Operating Room Nav Growth
- Laser Therapy Growth
- MR Drill and Access Growth
- 'Harmony' Software Launch
- New Routes of Administration
- Operational Cash Breakeven

2028+

Essential. Everywhere.

- $10B Potential Revenue Opportunity
- 'Combination Product' Regulatory Designation for multiple cell and gene therapy indications
- Meaningful Revenue from Sophisticated BioPharma Deal Structures beyond product sales including royalty and milestone payments, co-development
- One Unified Platform with both MR and Operating Room Capability and Workflows
- Additional Global Regulatory Approvals Beyond the U.S. and E.U.

*Including indications for all cell, gene, and device therapies enabled by ClearPoint Neuro technologies

The FDA & Global Notified Bodies **Recognize the Urgency**

1 Partner has received FDA approval for a neuro gene therapy that is co-labeled with ClearPoint

FDA NEWS RELEASE

FDA Approves First Gene Therapy for Treatment of Aromatic L-amino Acid Decarboxylase Deficiency

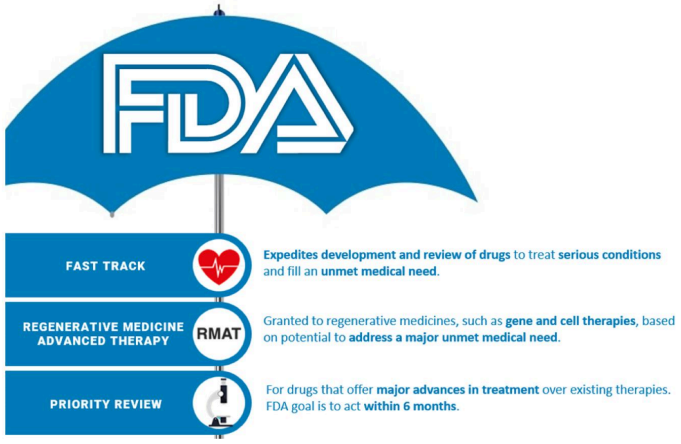
For Immediate Release:
November 14, 2024

The U.S. Food and Drug Administration approved Kebilidi (eladocagene exuparvovec-tneq), an adeno-associated virus vector-based gene therapy indicated for the treatment of adult and pediatric patients with aromatic L-amino acid decarboxylase (AADC) deficiency. Kebilidi is the first FDA-approved gene therapy for treatment of AADC deficiency.

"Clinical advancements in the field of gene therapy continue to lead to the discovery and availability of innovative treatment options for rare diseases that are otherwise difficult to manage," said Peter Marks, M.D., Ph.D., director of the FDA's Center for Biologics Evaluation and Research (CBER). "Today's approval underscores our commitment to help make safe and effective treatments available for patients in need."

The FDA also authorized the SmartFlow Neuro Cannula, an infusion tube inserted into a target in the brain (parenchymal tissue), to deliver Kebilidi. The SmartFlow Neuro Cannula is currently the only FDA authorized device indicated for use to administer Kebilidi. The FDA granted authorization of the SmartFlow Neuro Cannula to ClearPoint Neuro, Inc.

9 Partners have programs selected for expediated review - the FDA recognizes the urgency



Essential. Everywhere.

ClearPoint has **60+ Active BioPharma Programs across 20+ indications including DBS, LiTT**

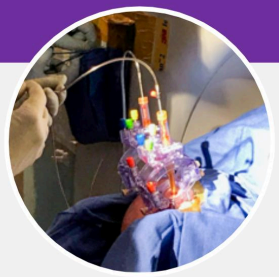
BENCHTOP TESTING

- Device Compatibility Testing
- Infusion Pump Testing
- Custom Device Development
- Performance Assessment
- Device Comparisons / Bridging

PRECLINICAL STUDIES

- Running Preclinical Studies
- Surgical Planning & Guidance
- Writing IACUC / Study Protocols
- Dosing and Surgical Support
- Post-Infusion Reporting

CLINICAL TRIALS



- Surgical Guidance
- Procedure Pre-Planning
- On-Site Clinical Support
- Inventory Management
- Data / Infusion Reporting

Essential. Everywhere.

Sophisticated Partnerships are Enabled by the **ClearPoint Ecosystem of Products & Services**

We provide the creative flexibility to structure agreements as an **essential and long-term supplier**

ClearPoint May Provide to BioPharma:		**ClearPoint May Secure from BioPharma:**
• Assurance of Supply	⟷	• Demand Planning
• Access to FDA Device Dossier	⟷	• Purchasing Commitments
• Redundant Global Manufacturing	⟷	• Minimum Device Purchases
• Contracted Commercial Pricing	⟷	• Co-Development Design Fees
• Licenses to Key Intellectual Property	⟷	• Strategic Retainer Agreements
• Custom Device Development	⟷	• Clinical Milestone Payments
• Clinical Specialist Procedural Support	⟷	• Premium Commercial Pricing
• Dedicated Inventory Locations	⟷	• Royalties on Drug Revenue
• Extensive Audit Access & Experience	⟷	• Preclinical Service Purchases
• Supply Continuity and Reliability	⟷	• Multiple Program Collaborations

Essential. Everywhere.

CLPT is like a **Portfolio of BioPharma without drug development costs or binary outcomes**

More than **30 million people** in the U.S. are estimated to suffer from **severe and debilitating neurological disorders:**

- Parkinson's Disease (≈1,000,000)
- Essential Tremor (≈7,000,000)
- Epilepsy (≈2,900,000)
- Huntington's Disease (≈41,000)
- Rare Childhood Genetic Disorders (≈25,000)
- Dementia and Alzheimer's Disease (≈6,900,000)
- Tumor and Glioblastoma (≈280,000)
- Severe OCD (≈1,000,000)
- Treatment Resistant Depression (≈2,900,000)
- ALS and Spinal Cord Injury (≈300,000)
- Stroke Rehabilitation (≈7,000,000)
- Neuropathic Pain (≈2,000,000)

ClearPoint Neuro is Diversified Across:

- 60+ BioPharma Partners
- 20+ Indications including device, cell and gene therapies
- Redundant Partners for multiple indications
- Many Partners with multiple programs
- Additional device treatments including DBS, Laser, BCI

Many shots on goal with a path to operational cash breakeven:

Our Company

The Future of Cell and Gene Therapy is Not Coming...**it is HERE TODAY**

9 Active Clinical-Stage Partners have been selected for expedited review, including:

	Indication	RMAT	Fast Track	Clinical Status
PTC Therapeutics	AADC Deficiency	-	-	**Approved**
uniQure	Huntington's Disease	✓	-	Trials in US, EU
BlueRock	Parkinson's Disease	✓	-	Trials in NorthAm
NEURONA THERAPEUTICS	Epilepsy (MTLE)	✓	-	Trials in the US
AskBio	Parkinson's Disease	✓	✓	Trials in US, EU
REGENXBIO	Hunter Syndrome (MPSII)	✓	✓	Trials in US, Brazil
Aspen Neuroscience	Parkinson's Disease	-	✓	Trials in the US
AVIADOBIO	Frontotemporal Dementia	-	✓	Trials in US, EU
Undisclosed	Friedreich's Ataxia	-	✓	Trials in the US

If just 1% of patients with diseases under expedited review are treated each year, at current ASPs that would yield more than $250M in additional CLPT revenue

CLEARPOINT NEURO EXECUTIVE SUMMARY

A UNIQUE PLATFORM TECHNOLOGY USED FOR CELL AND GENE THERAPY DELIVERY

15+ years building a complete drug delivery ecosystem including navigation solutions, predictive modeling, delivery devices, infusion monitoring software and clinical case support

A $10B POTENTIAL MARKET DIVERSIFIED ACROSS 60+ PARTNERS, 20+ INDICATIONS*

Combination device success, proprietary technology and deep FDA experience provide our BioPharma partners with a meaningful head start, and our investors with a Portfolio-like biotech strategy

100+ ACTIVE GLOBAL CENTERS

An expanding global installed base of regional treatment centers are scaling capacity to be ready for additional cell and gene therapy patients to be treated with a unified platform

CURRENT PORTFOLIO PROVIDES ACCESS TO A ≈$500M MARKET OPPORTUNITY TODAY

Evolved beyond the MRI and into operating room CT navigation, laser ablation therapy, surgical access tools and preclinical CRO services which fuel growth via new product launches and provide path to profitability

A GROWING & PASSIONATE TEAM

Our dedicated team of engineers, scientists and clinical specialists wake up every morning focused on the future of neurosurgery and drug delivery - *This is all that we do...*

*Including indications for all cell, gene, and device therapies enabled by ClearPoint Neuro technologies

Sources

Sources

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